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**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT OF CALIFORNIA**

JCS

ANTHONY TURANO,

Plaintiff,

vs.

ASTRAZENECA PHARMACEUTICALS, L.P., ASTRAZENECA, L.P., JOHNSON & JOHNSON COMPANY, AND JANSSEN PHARMACEUTICA PRODUCTS, L.P. A/K/A JANSSEN, L.P., A/K/A JANSSEN PHARMACEUTICA, L.P., A/K/A JANSSEN PHARMACEUTICA, INC.

Defendants.

C 06 0674

**COMPLAINT FOR NEGLIGENCE, FRAUD, FAILURE TO WARN, STRICT PRODUCTS LIABILITY AND BREACH OF WARRANTY**

**DEMAND FOR JURY TRIAL**

ANTHONY TURANO ("Plaintiff") alleges as follows:

**JURISDICTION AND VENUE**

1. This Court has jurisdiction pursuant to 28 USC § 1332, in that Plaintiff is a citizen of a State that is different from the State where Defendants are incorporated and have their principal place of business. The amount in controversy exceeds seventy-five thousand dollars ($75,000.00) as to each

Plaintiff. Venue pursuant to 28 USC § 1391(c) is proper because Defendants have sufficient contacts within the city and county of San Francisco, CA to subject it them to personal jurisdiction.

**PARTIES**

This is a civil action regarding damages that occurred as a result of Plaintiff's ingestion of atypical antipsychotic drugs that were designed, manufactured, promoted and/or sold by Defendants Astrazeneca Pharmaceuticals, L.P. ("AstraZeneca"), Astrazeneca, L.P. and/or their representatives under the name Seroquel (collectively the "Seroquel Defendants") and by Johnson & Johnson Company ("Johnson & Johnson") and Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc. ("Janssen") and/or its representatives under the name Risperdal (collectively the "Risperdal Defendants"). All collectively the "Defendants".

2. Plaintiff is a resident of the State of PENNSYLVANIA.

3. AstraZeneca is a Delaware business entity with its principal place of business in Wilmington, DE.

4. AstraZeneca is duly authorized to conduct business in the State of California and does business in California and in San Francisco.

5. At all times relevant here, AstraZeneca advertised, promoted, and sold Seroquel in California and San Francisco.

6. AstraZeneca expected or should have expected its acts to have consequences within the State of California and in San Francisco.

7. AstraZeneca, L.P., is a business entity with its principal place of business in Westborough, MA.

8. AstraZeneca, L.P. is duly authorized to conduct business in the State of California and does business in California and in San Francisco.

9. At all times relevant here, AstraZeneca, L.P. advertised, promoted, and sold Seroquel in California and San Francisco.

10. AstraZeneca, L.P. expected or should have expected its acts to have consequences within the State of California and in San Francisco.

11. Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, NJ.

12. Johnson & Johnson is duly authorized to conduct business in the State of California and does business in California and in San Francisco.

13. At all times relevant here, Johnson & Johnson advertised, promoted, and sold Risperdal in California and San Francisco.

14. Johnson & Johnson expected or should have expected its acts to have consequences within the State of California and in San Francisco.

15. Janssen is a New Jersey corporation with its principal place of business in Titusville, NJ.

16. Janssen is duly authorized to conduct business in the State of California and does business in California and in San Francisco.

17. At all times relevant here, Janssen advertised, promoted, and sold Risperdal in California and San Francisco.

18. Janssen expected or should have expected its acts to have consequences within the State of California and in San Francisco.

## SEROQUEL FACTS

19. At all relevant times, the Seroquel Defendants, through their agents, servants, and employees, designed, researched, manufactured, labeled, packaged, promoted marketed, and/or sold Seroquel, also known as quetiapine fumarate.

20. Seroquel is an "antipsychotic" medication, belonging to a class of drugs referred to as atypical antipsychotics.

21. In 1997, the FDA approved Seroquel for use in the United States.

22. In 2004 the FDA approved Seroquel for treatment of mania associated with bipolar disorder (manic-depressive illness).

23. Seroquel was marketed heavily by the Seroquel Defendants as safe and effective, promising fewer side effects than other similar treatments including the other atypical antipsychotics on the market.

24. The Seroquel Defendants, through their marketing department, their sales managers, and their field sales force promoted the drug for uses beyond its approved indications, offering incentives to doctors to increase prescriptions. Through these marketing efforts, the Seroquel Defendants were able to capture a larger market share in the antipsychotic market. These marketing efforts also included unlawfully and improperly promoting the drug for "off label" uses not approved by the FDA and not supported by medical science.

25. In 2005, Seroquel reached approximately $2.7 Billion in annual sales and controlled approximately 31% of the market share for atypical antipsychotics.

26. These marketing efforts by the Seroquel Defendants were designed and implemented to create the false impression in physicians' minds that Seroquel was safe and effective for their patients, and that it carried less risk of side effects and adverse reactions than other available treatments.

27. The marketing and promotion efforts of the Seroquel Defendants, their advertisers, and sales force served to overstate the benefits of Seroquel, and minimize and downplay the risks associated with the drug. These promotional efforts were made while fraudulently withholding important safety information from the physicians, the FDA, and the public. For example, the Seroquel Defendants were aware of numerous reports of diabetes associated with the use of Seroquel that were well beyond the

background rate and well beyond the rate for other antipsychotic agents. Further, the Seroquel Defendants knew and understated the nature and/or significance of the risk of Neuroleptic Malignant Syndrome (NMS.)

28. The product warnings for Seroquel in effect during the relevant time period were vague, incomplete or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians as well as consumer patients of the actual risks associated with this drug.

29. The use of Seroquel has been associated with an increased risk of developing diabetes mellitus, and the serious complications stemming therefrom including seizures, coma, death, liver disease, kidney disease, blindness, and other serious side effects including rapid weight gain, pancreatitis, increased thirst, and hypoglycemia.

30. In August 2003, news reports were issued that confirmed previous studies describing a link between the class of atypical antipsychotics and diabetes. These news reports described an increased incidence of diabetes in patients receiving Seroquel then in patients receiving older antipsychotics, or even other atypicals.

31. The Japanese label for Seroquel provides a detailed warning regarding the risks of diabetes associated with Seroquel, and specifically informs physicians regarding the necessity of medical monitoring of patients on Seroquel. At the time the Plaintiff first ingested Seroquel, the Seroquel Defendants had not adopted this safer, more accurate, label for the U.S. distribution of Seroquel.

32. Upon information and belief, the Japanese label warns specifically of the diabetes risk, prominently in the beginning of the package label stating:

- Quetiapine fumarate is contraindicated for use in patients with diabetes or a history of diabetes.
- Quetiapine fumarate should be used with caution in patients with risk factors for diabetes, including hyperglycemia, obesity or a family history of diabetes.

- Patients receiving quetiapine fumarate should be carefully monitored for symptoms of hyperglycemia and the drug should be discontinued if such symptoms occur. The symptoms of severe hyperglycemia include weakness, excessive eating, excessive thirst, and excessive urination.
- Physicians should educate patients and their family members about the risk of serious hyperglycemia associated with the quetiapine fumarate and how to identify the symptoms of hyperglycemia.

33. In a regulatory action overseas, the Ministry of Health, Labor, and Welfare in Japan has ordered a Dear Doctor warning for Seroquel after the ministry received reports of serious side effects, including death, since the drug's launch in that country.

34. While warning of the association of Seroquel with diabetes, glucose dysregulation, ketoacidosis, weight gain, and the need for medical monitoring in Japan, the Seroquel Defendants have failed to provide the same or similar warning to the U.S. public and prescribing physicians.

35. In September 2003, the Seroquel Defendants received a letter from the FDA informing them that the product packaging for Seroquel failed to convey appropriate risk information related to the drug's association with serious diabetes mellitus related conditions.

36. Despite having this information, the Seroquel Defendants failed to take action to correct the obvious defect with the Seroquel product labeling for several months. During this period the Seroquel Defendants did not pass on information regarding the diabetes mellitus risk to physicians or issue new labeling containing specific warnings.

37. As a direct result of Plaintiff's use of Seroquel, Plaintiff developed serious health problems. In addition, the conduct of the Seroquel Defendants has caused Plaintiff further damage including, but not limited to pain, suffering, mental anguish, the risk of early death and/or other complications, loss

of the enjoyment of life, medical expenses and other out-of-pocket losses and loss of past and future income.

## RISPERDAL FACTS

38. At all relevant times, the Risperdal Defendants, through their agents, servants, and employees, designed, researched, manufactured, labeled, packaged, promoted marketed, and/or sold Risperdal, also known as risperidone.

39. Risperdal is an "antipsychotic" medication, belonging to a class of drugs referred to as atypical antipsychotics and was approved for certain uses in the United States in 1994.

40. In 1997 the United States Food & Drug Administration ("FDA") approved Risperdal for use for the treatment of schizophrenia.

41. In 1999 the FDA approved Risperdal for use for the short-term treatment of acute mixed or manic episodes associated with bipolar disorder.

42. Risperdal is one of the Risperdal Defendants' top-selling drugs and produced approximately $3.5 billion in 2005 sales.

43. Since its introduction to the market, the FDA has received numerous reports of hypoglycemia, diabetes mellitus, worsening of existing diabetes, pancreatitis, and other severe injuries among patients, including children, who were prescribed Risperdal.

44. Shortly after the Risperdal Defendants began selling Risperdal, reports began to surface of Risperdal users who were suffering from hyperglycemia, acute weight gain, diabetes mellitus, pancreatitis, and other severe diseases and conditions. The Risperdal Defendants knew, or were reckless in not knowing, of these reports. Furthermore, the Risperdal Defendants were aware of studies and journal articles linking use of Risperdal with these and other severe and permanent hyperglycemia-related adverse events and diseases prior to and during the time that Decedent ingested Risperdal.

45. The diabetes risk associated with Risperdal is much higher than with older "typical" antipsychotic drugs.

46. In December 2000, the British Medical Journal found no clear evidence atypical antipsychotics, like Risperdal, Seroquel and Zyprexa, were more effective or better tolerated than conventional antipsychotics including Haldol and Thorazine.

47. In November 2003, the Journal of The American Medical Association compared Zyprexa with Haldol and found "no statistically significant advantages" of with Zyprexa for treatment of schizophrenia. The authors did notice significant difference among the costs of Haldol and Zyprexa per tablet: $0.02 versus $4.84 respectively.

48. The Risperdal Defendants' marketing efforts were designed and implemented to create the false impression in physicians' minds that Risperdal was safe and effective for their patients, and that it was more efficacious and carried less risk of side effects and adverse reactions than other available treatments.

49. The marketing and promotion efforts of the Risperdal Defendants overstated the benefits of Risperdal and minimized and downplayed the risks associated with the drug. These promotional efforts were made while withholding important safety information from the physicians, the FDA, and the public. For example, the Risperdal Defendants were aware of numerous reports of diabetes mellitus associated with the use of Risperdal, well beyond the background rate, and well beyond the rate associated with older antipsychotic agents.

50. On information and belief, in April 2002, the Japanese Health and Welfare Ministry issued Emergency Safety Information regarding the risk of diabetes mellitus, diabetic ketoacidosis, and other diabetic conditions, for patients prescribed atypical antipsychotics, including Risperdal.

51. In September 2003, the Risperdal Defendants received a letter from the FDA informing

them that the product packaging for Risperdal failed to convey appropriate risk information related to the drug's association with serious diabetes mellitus related conditions.

52. Despite having this information, the Risperdal Defendants failed to take action to correct the obvious defect with the Risperdal product labeling for several months. During this period the Risperdal Defendants did not pass on information regarding the diabetes mellitus risk to physicians or issue new labeling containing specific warnings.

53. On November 6, 2003, the Risperdal Defendants submitted supplemental New Drug Applications covering the addition of information to the Warnings section of the product labeling for Risperdal. The FDA approved the supplements and requested that the Risperdal Defendants issue a Dear Healthcare Provider letter communicating the important new risk information. Additionally the FDA asked the Risperdal Defendants to submit a copy of the letter to the FDA and to the MedWatch program.

54. Instead, on November 10, 2003, the Risperdal Defendants sent a Dear Healthcare Professional letter that misrepresented the risks. The letter stated in pertinent part:

> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics.

By sending this letter the Risperdal Defendants prevented physicians and patients from adequately understanding the risks associated with Risperdal.

55. In response to the misleading November 10, 2003 letter, the FDA issued a Warning Letter on April 19, 2004 to Ajit Shetty, M.D., CEO of Janssen, reprimanding the company. The FDA determined that the Dear Healthcare Provider letter omitted material information, minimized risks, and claimed superior safety to other drugs in its class without "adequate substantiation". Additionally, The Risperdal Defendants failed to comply with FDA requirements regarding post-marketing reporting by sending the letter. As a result, the FDA requested that The Risperdal Defendants immediately cease dissemination of promotional materials for Risperdal containing the same claims, or similar claims and warned that the FDA was continuing to evaluate all aspects of the promotional campaign for Risperdal.

56. In response to the FDA's Warning Letter, The Risperdal Defendants mailed another Dear Health Care Provider letter on July 21, 2004 admitting that the previous letter omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety in comparison to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act.

57. By reason of the acts and omissions of the Risperdal Defendants, Decedent suffered before his death and Plaintiff(s) have suffered damages.

58. Decedent used Risperdal in a foreseeable manner and the drug reached Decedent without substantial change in the drug's condition since manufacture or sale.

## ALLEGATIONS

59. The Defendants knew of the hazards associated with their atypical antipsychotic drugs, but the Defendants affirmatively and actively concealed information that clearly demonstrated the dangers

of their drugs and misled the public and prescribing physicians with regard to the material and clear risks associated with the drugs.

60. The Defendants did so with the intent that prescribing physicians would continue to prescribe their atypical antipsychotic drugs even though the Defendants knew that prescribing physicians would not be in a position to know the true risks of the drugs and the Defendants knew that prescribing physicians would rely upon the misleading information that the Defendants promulgated.

61. The Defendants, through their funding and control of certain studies concerning the effects of atypical antipsychotic drugs on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between their drugs and various diseases, all to the detriment of the public health, safety and welfare.

62. The Defendants improperly provided financial inducements to physicians to promote their atypical antipsychotic drugs for uses beyond those which the FDA approved and beyond those for which the drugs were medically accepted.

63. The Defendants improperly provided financial inducements to State Government officials to encourage acceptance of their atypical antipsychotic drugs for uses beyond those which the FDA approved and beyond those for which the drugs were medically accepted.

64. At all pertinent times, the Defendants purposefully and intentionally engaged in these activities, and continue to do so, knowing full well that when the general public,

65. including Plaintiff, used the atypical antipsychotic drugs as the Defendants intended they would be substantially at risk of suffering disease, injury and sickness.

66. The statements, representations and promotional schemes publicized by the Defendants were deceptive, false, incomplete, misleading and untrue.

67. The Defendants knew, or should have known, that their statements, representations and advertisements regarding their atypical antipsychotic drugs were deceptive, false, incomplete, misleading and untrue at the time of making such statements.

68. The Defendants had an economic interest in making such statements. Neither Plaintiff nor the physicians who prescribed the Defendants' atypical antipsychotic drugs had knowledge of the falsity or untruth of the Defendants' statements, representations and advertisements when prescriptions for the drugs were written.

69. Plaintiff and Plaintiff's physician had a right to rely on the Defendants' statements, representations and advertisements and Defendants knew that Plaintiff and Plaintiff's physician would be relying upon Defendants' statements. Each of the statements, representations and advertisements were material to the Plaintiff's purchase of the Defendants' atypical antipsychotic drugs in that the Plaintiff would not have purchased nor taken the drugs if Plaintiff had known that the Defendants' statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue.

70. Had Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' atypical antipsychotic drugs, Plaintiff would not have purchased or taken the drugs and could have chosen to request other prescription medications.

71. The Defendants negligently, recklessly and wantonly failed to warn Plaintiff, and the general public, of the risks associated with taking the Defendants' atypical antipsychotic drugs and failed to do so even after various studies, including their own, showed that there were problems concerning the risks of diabetes and diabetes-related injuries associated with the drugs.

72. The Defendants endeavored to deceive Plaintiff, and the general public, by not disclosing the findings of the various studies, including their own, which revealed problems concerning the dangers of the Defendants' atypical antipsychotic drugs.

73. The Defendants did not provide warnings and instructions that would have put Plaintiff, and the general public, on notice of the dangers and adverse effects caused by the Defendants' atypical antipsychotic drugs.

74. The Defendants designed, manufactured, distributed, sold and/or supplied their atypical antipsychotic drugs and otherwise placed the drugs into the stream of commerce in a defective and unreasonably dangerous condition, taking into consideration the utility of the drug and the risk to Plaintiff and the general public.

75. The Defendants' atypical antipsychotic drugs as designed, manufactured, distributed, sold and/or supplied by the Defendants were defective due to inadequate warnings, instructions and/or labeling.

76. The Defendants' atypical antipsychotic drugs as designed, manufactured, distributed, sold and/or supplied by the Defendants were defective due to inadequate testing before and after the Defendants knew of the various studies, including their own, evidencing the risks of diabetes and diabetes-related injuries associated with the drugs.

77. Plaintiff ingested the Defendants' atypical antipsychotic drugs and as a result suffered emotional and personal injury and economic loss.

**DISCOVERY RULE & FRAUDULENT CONCEALMENT**

78. The nature of Plaintiff's injuries and their relationship to Defendants' drugs were inherently undiscoverable. Consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew or through the exercise of reasonable care and diligence should have known of the existence of his claims against Defendants. Plaintiff did not discover, and through the exercise of reasonable care and due diligence could not have discovered his injuries earlier.

79. Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct. Under appropriate application of the "discovery rule," Plaintiff's suit was filed well within the applicable statutory limitations period.

80. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and Defendants' tortious conduct.

## FIRST CAUSE OF ACTION

## NEGLIGENCE

81. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above with the same force and effect as if more fully set forth herein.

82. The Defendants had a duty to exercise reasonable care when they designed, researched, manufactured, labeled, packaged, promoted marketed, and/or sold the drugs ingested by Plaintiff, including a duty to ensure that the drugs did not cause users to suffer from undisclosed dangerous side effects when used alone or in foreseeable combination with other drugs.

83. The Defendants were negligent when they designed, researched, manufactured, labeled, packaged, promoted marketed, and/or sold their atypical antipsychotic drugs, in that, among other things, they:

a. Failed to accompany the product with proper warnings regarding all possible adverse side effects associated with the use of their drugs;

b. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their drugs;

c. Failed to provide adequate training and instruction to medical care providers for appropriate use of their drugs;

d. Failed to warn Plaintiff while actively encouraging the sale of their drugs, either directly or indirectly (through Plaintiff's prescribing physician), orally or in writing, about the following:

1. The need for diagnostic tests to be performed on the patient prior to ingesting the Defendants' atypical antipsychotic drugs to discover and ensure against potentially fatal side effects; or

2. The need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal side effects;

e. Failed to warn that the risks associated with the ingestion of their drugs exceeded the risks of other alternative forms of medication;

f. Failed to effectively warn about the increased danger and potentially fatal relationship in combining the use of their drugs either together or with various other drugs for use in treatment of Plaintiff's condition;

g. Negligently marketed their drugs despite the fact that the risks of the drug were so high and the benefits of the drug were so low that no reasonable pharmaceutical company, exercising due care, would have done so;

h. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of their drugs from prescribing physicians and the consuming public; and that had prescribing physicians and the consuming public known of such facts, the Defendants' atypical antipsychotic drugs would never have been prescribed to, or used by, Plaintiff;

i. Remained silent despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of ingestion of their drugs and did so because the prospect of huge profits outweighed health and safety issues, all to the significant detriment of Plaintiff;

j. Failed to perform their post-manufacturing and continuing duty to warn which arose when they knew, or with reasonable certainty should have known, that their drugs were being prescribed in a dangerous manner;

k. Unlawfully and improperly marketed and promoted their atypical antipsychotic drugs for "off label" uses beyond those uses approved by the FDA or supported by medical science;

l. Unlawfully and improperly provided financial incentives to physicians and others to prescribe the drugs and approve its use;

m. Were otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard with respect to the rights of Plaintiff;

n. Continued to market the drugs to consumers, including when there were safer alternative methods of treating Plaintiff's condition, despite the fact that Defendants knew or should have known that the drugs caused unreasonable, dangerous side effects; and

o. Knew or should have known that consumers such as this Plaintiff would foreseeably suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.

84. As a direct and proximate result of the Plaintiff's ingestion of Defendants' drugs and the acts and failures to act by the Defendants, Plaintiff developed serious health problems and suffered damages including but not limited to past, present and future pain and suffering, serious and permanent physical injuries, loss of enjoyment of life, past and future medical expenses, and past and/or future lost wages.

85. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent; were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' drugs, and for the primary purpose of increasing Defendants' profits from the sale and distribution of their drugs Zyprexa. As such Plaintiff is entitled to exemplary damages.

## SECOND CAUSE OF ACTION

## FRAUD

86. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above with the same force and effect as if more fully set forth herein.

87. The Defendants either knew or should have known that their drugs were dangerous and not as effective for their purpose as represented and posed greater risks than disclosed.

88. The Defendants were under a duty to disclose this information to the Plaintiff because the Defendants made representations and partial disclosures concerning the nature and quality of their products that they had a duty to correct. The Defendants were in a superior position to know the true state of the facts about the dangerous and defective nature of the drugs and the known risks to the

Plaintiff. These deliberate and/or intentional omissions of material facts and misrepresentations include but are not limited to:

a. Suppressing, failing to disclose and mischaracterizing the known risks of ingesting the Defendants' drugs;

b. Omitting material information showing that the Defendants' drugs were no more effective than other antipsychotic drugs available on the market;

c. Failing to timely and fully disclose the actual results of clinical tests and studies related to the Defendants' drugs;

d. Failing to issue adequate warnings concerning the risks and dangers of ingesting the drugs, which would disclose the nature and extent of the side effects of the Defendants' drugs;

d. Failing to disclose that adequate, standard and/or generally accepted standards for pre-clinical and clinical testing had not been done;

e. Failing to disclose that adequate, standard and/or generally accepted standards for post-marketing testing had not been done;

f. Making the representations concerning the safety, efficacy and benefits of the Defendants' drugs as detailed in this complaint without full and adequate disclosure of the underlying facts which rendered such statements false and misleading;

g. Unlawfully and improperly marketed and promoted their atypical antipsychotic drugs for "off label" uses beyond those uses approved by the FDA or supported by medical science; and

h. Unlawfully and improperly provided financial incentives to physicians and others to prescribe their drugs and approve its use.

89. Plaintiff did not know, and could not learn, the material facts and important information that the Defendants omitted and suppressed. The facts and information suppressed and concealed by the Defendants are material, and of such a nature that it can be reasonably presumed that the suppression and concealment of such facts caused, contributed to, and/or was a substantial factor in the Plaintiff's decision to ingest Defendants' drugs.

90. As a direct and proximate result of the Plaintiff's ingestion of Defendants' drugs and the aforesaid acts and failures to act by the Defendants, Plaintiff developed serious health problems and suffered damages including but not limited to past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, past and future medical expenses, and past and/or future lost wages.

91. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent; were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' drugs, and for the primary purpose of increasing Defendants' profits from the sale and distribution of their drugs. As such Plaintiff is entitled to exemplary damages.

## THIRD CAUSE OF ACTION

## STRICT LIABILITY FAILURE TO WARN

92. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above with the same force and effect as if more fully set forth herein.

93. The Defendants' drugs were unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects. The warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects.

94. The Defendants' drugs were defective due to inadequate post-marketing warning or instruction because the Defendants failed to provide adequate warnings to users or consumers of the drugs and continued to aggressively promote these dangerous and defective drugs.

95. As a result of the foregoing, the drugs were defective and unreasonably dangerous products.

96. As a direct and proximate result of Plaintiff's ingestion of the Defendants' drugs and the aforesaid acts and failures to act by the Defendants, Plaintiff developed serious health problems and

suffered damages including but not limited to past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, past and future medical expenses, and past and/or future lost wages.

97. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent; were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' drugs, and for the primary purpose of increasing Defendants' profits from the sale and distribution of their drugs. As such Plaintiff is entitled to exemplary damages.

## FOURTH CAUSE OF ACTION
## STRICT PRODUCT LIABILITY

98. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above with the same force and effect as if more fully set forth herein.

99. The Defendants' drugs were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

100. Alternatively, the Defendants' drugs were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers and/or distributors, they were unreasonably dangerous, more dangerous than an ordinary consumer would expect, and they were more dangerous than other antipsychotic drugs.

101. There existed, at all times material hereto, safer alternative medications.

102. The Defendants did not perform adequate testing on their drugs. Adequate testing would have shown that the drugs caused serious adverse effects with respect to which full and proper warnings that accurately and fully reflected symptoms, scope and severity should have been made.

103. As a direct and proximate result of Plaintiff's ingestion of Defendants' drugs and the aforesaid acts and failures to act by the Defendants, Plaintiff developed serious health problems and suffered damages including but not limited to past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, past and future medical expenses, and past and/or future lost wages.

104. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent; were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' drugs, and for the primary purpose of increasing Defendants' profits from the sale and distribution of their drugs. As such Plaintiff is entitled to exemplary damages.

**FIFTH CAUSE OF ACTION**
**BREACH OF EXPRESS WARRANTY**

105. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above with the same force and effect as if more fully set forth herein.

106. The Defendants expressly warranted that their drugs were safe and more effective than other antipsychotic drugs.

107. The Defendants' drugs did not conform to these express representations because the drugs are not safe, have high levels of serious, life-threatening side effects and are not more effective than other drugs.

108. As a direct and proximate result of Plaintiff's ingestion of Defendants' drugs and the aforesaid acts and failures to act by the Defendants, Plaintiff developed serious health problems and suffered damages including but not limited to past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, past and future medical expenses, and past and/or future lost wages.

109. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent; were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' drugs, and for the primary purpose of increasing Defendants' profits from the sale and distribution of their drugs. As such Plaintiff is entitled to exemplary damages.

## SIXTH CAUSE OF ACTION
## BREACH OF IMPLIED WARRANTY

110. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above with the same force and effect as if more fully set forth herein.

111. At the time the Defendants marketed, sold and distributed their drugs for use by Plaintiff and the consuming population, the Defendants knew of the use for which the drugs were intended and impliedly warranted the drugs to be of merchantable quality and safe and fit for such use.

112. Plaintiff reasonably relied upon the skill and judgment of the Defendants as to whether their drugs were of merchantable quality and safe and fit for their intended use.

113. Contrary to such implied warranties, the Defendants' drugs were not of merchantable quality or safe or fit for their intended use because the drugs were and are unreasonably dangerous and unfit for the ordinary purposes for which they were used as described above.

114. As a direct and proximate result of Plaintiff's ingestion of Defendants' drugs and the aforesaid acts and failure to act by the Defendants, Plaintiff developed serious health problems and suffered damages including but not limited to past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, past and future medical expenses, and past and/or future lost wages.

115. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent; were done with a conscious disregard for the health,

safety and rights of Plaintiff and other users of Defendants' drugs, and for the primary purpose of increasing Defendants' profits from the sale and distribution of their drugs. As such Plaintiff is entitled to exemplary damages.

## SEVENTH CAUSE OF ACTION
## CONCEALMENT, SUPPRESSION, OR OMISSION OF MATERIAL FACTS

116. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above with the same force and effect as if more fully set forth herein.

117. The Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of their drugs, including but not limited to the risks of diabetes mellitus and other injuries. Further, the Defendants purposely downplayed and understated the serious nature of the risks associated with use of their drugs in order to increase the sales of those drugs.

118. The Defendants knew or should have known (and would have known had appropriate testing been done) that use of their drugs caused serious and potentially life-threatening side effects.

119. The Defendants engaged in calculated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of their drugs and did so because the prospect of significant future profits caused them to ignore concerns regarding health and safety issues, all to the significant detriment of the public, including the Plaintiff.

120. Many safer and less expensive antipsychotics were available to patients being treated with the Defendants' drugs.

121. The Defendants purposefully downplayed the side effects or provided misinformation about adverse reactions and potential harms from their drugs, and succeeded in persuading large segments of the relevant consumer market to request their drugs and large segments of the medical community to prescribe their drugs, despite both the lack of efficacy and the presence of significant dangers, as set forth herein.

122. The Defendants had a post-manufacturing and continuing duty to warn, which arose when they knew, or with reasonable care should have known, that their drugs were injurious or fatal.

123. The Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of their drugs, including but not limited to the risks of death, disease and other health problems associated with the use of their drugs. The Defendants have purposely downplayed and/or understated the serious nature of the risks associated with the use of their drugs and have implicitly encouraged the use of these drugs despite knowledge of the dangerous side effects that their drugs presents to the patient population.

124. Defendants purposefully and knowingly promoted their drugs for "off label" uses beyond the scope of the FDA approved uses and beyond those uses supported by medical science.

125. Defendants unlawfully provided financial incentives to physicians and others to prescribe and approve "off label" uses.

126. The Defendants knew or should have known, and would have known had appropriate testing been done, that the use of their drugs caused the serious and potentially life threatening side effects.

127. The Defendants' actions as set forth herein constitute knowing omission, suppression or concealment of material facts, made with the intent that others would rely upon such concealment, suppression or omission, in connection with the marketing, sale and use of their drugs.

128. In fact, the Plaintiff directly and/or through prescribing physicians was induced by the Defendants' omissions and suppression and concealment of facts to use Defendants' drugs.

129. As a direct and proximate result of the Plaintiff's ingestion of Defendants' drugs caused by the aforesaid acts and failures to act by the Defendants, Plaintiff suffered damages including but not limited to past, present and future pain and suffering, serious physical injuries, loss of enjoyment of life, past and future medical expenses, and past and/or future lost wages.

130. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent; were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' drugs, and for the primary purpose of increasing Defendants' profits from the sale and distribution of their drugs. As such Plaintiff is entitled to exemplary damages.

## PRAYER FOR RELIEF

**WHEREFORE,** Plaintiff demands judgment against AstraZeneca and AstraZeneca, L.P. as follows:

1. General damages in the amount of at least $10,000,000.00;
2. Exemplary damages in the amount of at least $50,000,000.00;
3. Costs of suit; and
4. For such other relief as the court deems proper.

**WHEREFORE,** Plaintiff demands judgment against Johnson & Johnson as follows:

1. General damages in the amount of at least $10,000,000.00;
2. Exemplary damages in the amount of at least $50,000,000.00;
3. Costs of suit; and

4. For such other relief as the court deems proper.

Dated: January 30, 2006

LEVIN SIMES & KAISER LLP

By: _____
William A. Levin
Laurel L. Simes
Jeffrey A. Kaiser

Attorneys for Plaintiff

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury as to all issues.

LEVIN SIMES & KAISER LLP

By: _____
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Laurel L. Simes
Jeffrey A. Kaiser

Attorneys for Plaintiff